K030353

APR 2 5 2003

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Eagle Vision, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis Tennessee, 38133 USA
OFFICIAL CORRESPONDENT	Billy Hannaford RA/QA Manager Eagle Vision, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis Tennessee, 38133 USA Tel: (901) 380-7000 FAX: (901) 380-7001 e-mail: billyh@eaglevis.com
TRADE NAME:	Eagle Vision Lacrimal Stents and Intubation Sets
COMMON NAME:	Monocanalicular stents Lacrimal Intubation Sets
CLASSIFICATION NAME:	Probe, lacrimal
DEVICE CLASSIFICATION:	Class II per 21 CFR § 886.4350
PRODUCT CODE	86 (HNL)
PREDICATE DEVICE:	EV™ Monocanalicular Stent (cleared under K883233), the Lacrimal Intubation Set & DCR Set (cleared under K990672), and the Ritleng Bicanaliculus Intubation Set (cleared under K955671)

SUBSTANTIALLY EQUIVALENT TO:

The MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set are substantially equivalent to the EV™ Monocanalicular Stent (cleared under K883233), the Lacrimal Intubation Set & DCR Set (cleared under K990672), and the Ritleng Bicanaliculus Intubation Set (cleared under K955671), respectively.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set are lacrimal stents and delivery systems.

INDICATION FOR USE:

The MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set are lacrimal stents and their delivery systems. They are intended for use in lacrimal system reconstruction. This includes, but is not limited to, treatment of: epiphora in infants or adults; canalicular pathologies such as stenosis; obstruction or laceration; and conditions requiring dacryocystorhinostomy (conventional or laser); or imperforation of the nasolacrimal duct in an infant.

TECHNICAL CHARACTERISTICS:

The MonoStent™ Monocanalicular Stents consist of a length of silicone tubing, with a silicone punctum plug molded perpendicularly onto one end of the tubing. A stainless steel stylet is provided with the stent to assist in the insertion of the silicone tubing.

The EagleVision® Lacrimal Intubation Set is comprised of stents for use in monocanalicular and bicanalicular intubation procedures. The stents are made of medical grade silicone tubing that is attached to malleable stainless steel probes. The intubation set allows for probing and stenting as a one step procedure.

The EagleVision® K Type Lacrimal Intubation Set is comprised of stents for use in monocanalicular and bicanalicular intubation procedures. The stents are made of silicone probes attached with a silicone rod.

PERFORMANCE DATA:

Descriptive characteristics were sufficient for assurance of equivalence. A comprehensive literature and MDR review was conducted to demonstrate that the MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set are substantially equivalent to the EV™ Monocanalicular Stent (cleared under K883233), the Lacrimal Intubation Set & DCR Set (cleared under K990672), and the Ritleng Bicanaliculus Intubation Set (cleared under K955671), respectively.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set are substantially equivalent to the EV™ Monocanalicular Stent (cleared under K883233), the Lacrimal Intubation Set & DCR Set (cleared under K990672), and the Ritleng Bicanaliculus Intubation Set (cleared under K955671), respectively. All of the devices have the same indication for use, "...for use in lacrimal system reconstruction ..." The devices have similar designs and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2003

Eagle Vision, Inc.
c/o Mr. Billy Hannaford
RA/QA Manager
8500 Wolf Lake Drive, Suite 110
Memphis Tennessee, 38133 USA

Re: K030353
Trade/Device Name: Eagle Vision Lacrimal Stents and Intubation Sets
Regulation Number: 886.4350
Regulation Name: Monocanalicular stents; Lacrimal Intubation Sets
Regulatory Class: II
Product Code: HNL
Dated: January 31, 2003
Received: February 3, 2003

Dear Mr. Hannaford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030353

Device Name: The MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set

Indications for Use:

The MonoStent™ Monocanalicular Stent, the EagleVision® Lacrimal Intubation Set, and the EagleVision® K Type Lacrimal Intubation Set are lacrimal stents and their delivery systems. They are intended for use in lacrimal system reconstruction. This includes, but is not limited to, treatment of: epiphora in infants or adults; canalicular pathologies such as stenosis; obstruction or laceration; and conditions requiring dacryocystorhinostomy (conventional or laser); or imperforation of the nasolacrimal duct in an infant.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susannah Jones

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K030353

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)